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IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

MARGARET M. HECKLER, SECRETARY OF HEALTH AND HUMAN SERVICES,
Petitioner,

v.

AMERICAN HOSPITAL ASSOCIATION, *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit

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BRIEF OF THE RESPONDENTS AMERICAN MEDICAL ASSOCIATION, ET AL., IN OPPOSITION

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QUESTION PRESENTED

Whether Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794, authorizes:

(a) a direct federal role investigating and regulating individual treatment decisions involving severely impaired newborn infants, which intrudes on the states' traditional responsibilities for regulating parent-child and physician-patient relationships; and

(b) the inevitable creation of a body of "504 malpractice law" for determining whether individual treatment decisions in the complex and rapidly evolving area of medical care for severely impaired newborns are "reasonable" or "unreasonable" under federal standards.

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BRIEF OF THE RESPONDENTS AMERICAN MEDICAL ASSOCIATION, ET AL., IN OPPOSITION

The American Medical Association ("AMA"), the American College of Obstetricians and Gynecologists, the Association of American Medical Colleges, the American Academy of Family Physicians, the Hospital Association of New York State, the American Hospital Association and certain individual physicians ("respondents AMA *et al.*") oppose the petition for a writ of certiorari filed by Margaret M. Heckler ("the Secretary"), the Secretary of Health and Human Services ("HHS").

The Secretary seeks review of a decision by the United States Court of Appeals for the Second Circuit invalidating a regulation issued by the Secretary pursuant to Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794 ("the 504 Regulation") (Pet. App. 53a-58a), which authorizes direct federal investigation and regulation of individual treatment decisions made by parents on behalf of their severely impaired children in consultation with

the physician of their choice. The regulation also places "*independent federal dut*[*ies*]" on hospitals and other providers of health services with regard "to the treatment" of severely impaired infants. Pet. 27 n.22 (emphasis supplied).

Review by this Court is not warranted. First, Section 504 clearly does not authorize direct federal investigation of individual treatment decisions involving impaired newborns—a federal role that would unnecessarily duplicate and inevitably subvert the states' traditional responsibilities for regulating individual parent-child and doctor-patient relationships. Second, the federal interest with respect to treatment of impaired newborns is reflected not in the 504 Regulation promulgated solely by the Secretary but in the 1984 Child Abuse Amendments, Pub. L. No. 98-457, 98 Stat. 1749 (1984), enacted by the Congress last fall after the 504 Regulation had been invalidated. This new legislation uses a state grant program and state agencies to address federal concerns and expressly repudiates a direct federal regulatory role and creation of a federal bureaucracy to enforce the federal "504 malpractice" standards which are inherent in the Secretary's voided approach.

STATEMENT

The Secretary's statement of the case (Pet. 2-11) is profoundly misleading because it fails to describe adequately or ignores completely the following crucial dimensions of the problem of proper care for impaired newborns: the historic state law framework which regulates parent-child and physician-patient relationships; the complex medical and ethical issues raised by treatment decisions for impaired newborns; the growth of voluntarily-created, hospital-based infant care review committees which provide a non-governmental response to the difficult issues that arise in this area; the facts of *United States* v. *University Hospital*, 729 F.2d 144 (2d Cir. 1984) (Pet. App. 4a-47a), which demonstrate fully how overbearing, intrusive and unnecessary is the federal gov-

ernment's attempt under Section 504 to regulate individual treatment decisions directly; and the Congress' explicit decision in the 1984 Child Abuse Amendments to reject, on policy grounds, the direct federal investigatory and regulatory role advanced by the Secretary here.

(1) *The State Law Framework.* The public dialogue about appropriate medical treatment of severely impaired newborn infants takes place within an historic state law framework which cedes to parents the ultimate responsibility for making decisions about treatment of their seriously ill children. 50 Fed. Reg. 14880 (April 15, 1985).[1] Parental treatment decisions on behalf of their children are controlling, except in the most extreme cases when state courts have determined that a decision not to authorize treatment constitutes "medical neglect" of children by their parents. *Id.*

All fifty states have child protective service agencies which are generally responsible for investigating reports of child abuse and neglect by parents (including "medical neglect"), counseling families and, where necessary, instituting court actions to remove the parent as decision maker for the child. *Id.* at 14878. Moreover, most hospitals have established procedures for working with the state child protective service agencies and seeking state court orders directing that appropriate medical treatment be given to an infant when the parents are clearly not acting in the best interest of the child. *See* 49 Fed. Reg. 1631 (1984).

State law also has historically governed the relationship between patients and physicians.[2] Unless parents

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[1] This Court already has recognized the primacy of the parents' role in making difficult treatment decisions for their children. *See Parham* v. *J.R.*, 442 U.S. 584, 602 (1979) (historically law has recognized that natural bonds of affection lead parents to act in the best interests of their children).

[2] *See Barsky* v. *Board of Regents*, 347 U.S. 442 (1954); *Linder* v. *United States*, 268 U.S. 5 (1925); *Dent* v. *West Virginia*, 129 U.S. 114 (1889).

consent to treatment, a physician commits battery if he or she operates on a minor. *See* note 16, *infra*. All states have mandatory reporting statutes which require physicians (and other health care professionals) to inform the state child protective service agency of known or suspected instances of medical neglect by parents.[3] Moreover, once a physician has been engaged by a patient (or by a parent on behalf of a minor patient) and consent to treatment has been given, then under state statutory or common law the physician has a legal duty to provide appropriate medical care until the doctor-patient relationship is terminated by giving the patient due notice and the opportunity to obtain other medical care. If the physician withdraws before these conditions are satisfied, then he or she is liable for damages under the doctrine of patient abandonment.[4]

The Secretary attempts to mislead this Court by vaguely citing to the "Baby Doe of Indiana" case ("Bloomington Baby Doe") to illustrate the "problem" with the historic state law framework which, in her view, justifies a direct federal role. Pet. 2-3, 20. But, as discussed *infra*, pp. 27-28, both private health care providers

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[3] *See generally* S. Cohen & A. Sussman, Reporting Child Abuse and Neglect (1975); Besharov, *The Legal Aspects of Reporting Known and Suspected Child Abuse and Neglect*, 23 Vill. L. Rev. 458 (1977-1978).

[4] *See* 1 D. Louisell & H. Williams, Medical Malpractice ¶¶ 4.12, 8.08 (Rev. ed. 1984); A. Holder, Medical Malpractice Law 374-393 (1975). Widely accepted principles of medical ethics impose a similar duty on physicians to continue necessary treatment until the physician-patient relationship has been properly terminated in a manner which allows engagement of another physician. AMA, Current Opinions of the Judicial Council § 8.10 (1984).

In addition, medical licensing statutes in many states provide for the revocation or suspension of a physician's license, or other disciplinary action, upon a finding, *inter alia*, that the physician has abandoned his or her patient by refusing to provide needed treatment. *See, e.g.*, Cal. Bus. & Prof. Code § 2234 (West 1985 Supp.); Ill. Ann. Stat. ch. 111, § 4433 (Smith-Hurd 1984-85 Supp.); N.Y. Educ. Law § 6509 (McKinney's 1984 Supp.).

and state executive branch officials sought judicial review of the parental treatment decision in that case. Two different state court judges refused to overturn the parents' treatment choice, and those state *judicial* decisions are clearly not subject to federal regulation under Section 504. The actions of health care providers and state officials in taking a rare case of questionable parental decisionmaking to state court shows that state laws and institutions are working.

(2) *Medical and Ethical Context: The Growth of Infant Care Review Committees.* The question of what sort of medical treatment, if any, should be given to severely impaired newborn infants is "one of the most difficult and sensitive medical and ethical problems facing our society." *American Academy of Pediatrics* v. *Heckler*, 561 F. Supp. 395, 396 (D.D.C. 1983) (Gesell, J.). The birth of such an infant is often an unexpected and traumatic event for parents, who are confronted with the necessity of making difficult life or death treatment decisions with little advance warning. *See* R. Stinson & P. Stinson, The Long Dying of Baby Andrew (1983). The difficulties for parents become acute when a particular condition is so serious that severe disability will remain even after treatment of that condition or when an infant has multiple impairments, one that is correctable and one, like anencephaly (entire or substantial absence of a brain), which will have an enormous, adverse impact on the child.[5]

In some cases involving impaired newborn infants, physicians can predict with a relative degree of confidence that a particular course of treatment is likely to be beneficial or futile.[6] But there is a significant area of

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[5] *See generally* A. Rudolph, Pediatrics (17th ed. 1983); W. Nelson, Textbook of Pediatrics (R. McKay & V. Vaughan ed. 1975).

[6] *See* Affidavit of Peter A.M. Auld, M.D., professor of Pediatrics and Obstetrics and Perinatal Medicine at Cornell University Medical College, ¶ 2. Plaintiffs-respondents AMA *et al.* submitted affi-

uncertainty in which the results and consequences of a given course of treatment are simply unpredictable and the selection of an appropriate course of treatment becomes commensurately more difficult. As the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research stated in its recent report, Deciding to Forego Life-Sustaining Treatment 220 (1983) [*"President's Commission Report"*]:

> Much of the difficulty in these [ambiguous] cases arises from factual uncertainty. For the many infants born prematurely, and sometimes for those with serious congenital defects, the only certainty is that without intensive care they are unlikely to survive; very little is known about how each individual will fare with treatment. Neonatology is too new a field to allow accurate predictions of which babies will survive and of the complications, handicaps, and potentials that the survivors might have. (Footnote omitted.)

Recent advances in neonatal medicine have also exacerbated the uncertainty in treatment decisions. As the President's Commission Report explained (at p. 198):

> [M]edicine's increased ability to forestall death in seriously ill newborns has magnified the already difficult task of physicians and parents who must attempt to assess which infants will benefit from various medical interventions, and which will not. Not only does this test the limits of medical certainty in diagnosis and prognosis, it also raises profound ethical issues.

To address the difficult ethical issues which can be raised by the birth of a severely impaired child, the President's Commission Report (at p. 225-228) repudi-

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davits and other evidentiary material in support of their motion for summary judgment in this case. In her defense, the Secretary did not submit *any* testimonial evidence on medical issues. Citations to affidavits in this opposition thus refer to the uncontested testimony submitted to the District Court by the AMA *et al.*

ated an increased federal role like the one advanced by the Secretary in the 504 Regulation and, instead, recommended the voluntary formation of infant care review committees. Medical associations have also advocated the formation of such committees.[7] These committees deal directly with the fundamental problem in this sensitive area: lack of information and perspective by the parents who must make decisions for their severely impaired infant. *President's Commission Report* at 227. Such committees are comprised of health professionals and, often, of individuals trained in other specialties such as religion, social work, ethics and law. The committees offer parents information, counseling and, where appropriate, review of proposed treatment decisions made in consultation with the attending physician. At present, many hospitals with intensive care units for neonates have some form of special review process for these difficult cases, and the number of infant care review committees is growing rapidly. 50 Fed. Reg. 14887 (April 15, 1985).

(3) *The Voided 504 Regulation.* Instead of following the recommendation of the President's Commission Report, the Secretary adopted the approach invalidated below which injects the federal government directly into individual treatment decisions. The 504 Regulation contains four mandatory provisions which were declared unlawful and enjoined in this case.[8] (i) The regulation re-

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[7] *See President's Commission Report* at 227-228; AMA, Judicial Council Report, *Guidelines for Ethics Committees in Health Care Institutions*, 253 J.A.M.A. 2698 (1985); American Academy of Pediatrics, *Guidelines for Infant Bioethics Committees* (1984).

[8] *See* 45 C.F.R. §§ 84.55(b)-(e). (Pet. App. 54a-58a.) The 504 Regulation also contains several non-mandatory provisions which were not challenged in this case. First, the regulation encourages, but does not require, health care providers to establish infant care review committees and sets forth a model rule for the establishment of such committees. 45 C.F.R. §§ 84.55(a), (f). (Pet. App. 53a-54a, 58a-62a.) Second, an Appendix to the regulation contains "interpretative guidelines" illustrating how the rule might apply to

quires recipient hospitals to post a notice, where health care professionals will see it, which states, in part, that discriminatory failure to provide "medically beneficial" treatment to an impaired newborn violates Section 504. The phrase "medically beneficial treatment" is not defined in the required notice. The notice must include the telephone number of a 24-hour a day hotline where any person may call federal officials to report suspected violations, even if such reports are based on nothing more than rumor. 45 C.F.R. § 84.55(b). (Pet. App. 54a.)

(ii) The 504 Regulation provides that recipient state child protective service agencies must establish and maintain in written form "methods of administration and procedures to assure that the agency utilizes its full authority *pursuant to state law* to prevent instances of unlawful *medical neglect* of handicapped infants." 45 C.F.R. § 84.55(c) (emphasis supplied). (Pet. App. 56a.) These "methods and procedures" include a *federal* requirement that physicians and other health care providers must report on a timely basis to the state agency "circumstances which they determine to constitute *known* or *suspected instances of unlawful medical neglect* of handicapped infants." *Id.* (emphasis supplied).

(iii) The 504 Regulation grants HHS expedited access to pertinent medical records and facilities and authorizes expedited investigations whenever HHS determines that immediate action is necessary to protect the life or health of an infant. 45 C.F.R. § 84.55(d). (Pet. App. 58a.)

(iv) The 504 Regulation also authorizes expedited action by HHS against federal fund recipients to effect compliance with Section 504, including court action. 45 C.F.R. § 84.55(e). (Pet. App. 58a.)

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particular treatment situations. 45 C.F.R. § 84.55, Appendix C, ¶ (a). (Pet. App. 66a-68a.) Finally, the Appendix sets forth "interpretative guidelines" for the conduct of HHS investigations. 45 C.F.R. § 84.55, Appendix C, ¶ (b). (Pet. App. 68a-72a.)

(4) *The Decisions Below.* The actions of the Secretary in *University Hospital*—which are conspicuously absent from her description of that case (Pet. 8-9)—perfectly illustrate the intrusive and unnecessary role of the federal government in second-guessing parents and state authorities under Section 504. After Baby Jane Doe was born with multiple birth defects on October 11, 1983, her parents decided not to authorize certain surgery following consultation with "several physicians, nurses, religious advisors, a social worker, and members of their family." (Pet. App. 6a.) A third party, unrelated to Baby Jane Doe, filed suit in New York State court seeking appointment of a guardian *ad litem* and an order directing that the surgery be performed. The trial court granted this request, but was immediately overruled by the Appellate Division, which determined that the parents' decision was in the best interests of the child. (Pet. App. 7a.) The New York Court of Appeals affirmed. (Pet. App. 7a-8a.)

While the state court proceedings were still in progress, the federal government, which had received a 504 complaint from an unidentified citizen, referred the matter to the New York State child protective service agency. That agency concluded on November 7, 1983 that there was no cause for state intervention against the parents. (Pet. App. 8a.) Without waiting for the state agency to make its determination, HHS in late October began its own direct Section 504 investigation. University Hospital declined to give Baby Jane Doe's medical records to HHS, based in part on the parents' refusal to release them. On November 2, 1983, *before* the state child protective service agency had reached a decision, HHS brought an action under Section 504 in federal court seeking access to the records. The Department then persisted in its suit even after the state agency concluded that no state intervention was warranted under New York's child neglect statute. (Pet. App. 8a-10a.) To protect their interests, Baby Jane Doe's parents were forced to intervene.

Baby Jane Doe's parents were thus required to defend not only a state court action and a state child protective service agency inquiry but a separate and independent federal lawsuit instituted by the United States. This harassing federal action exposed the parents to continued, unwanted publicity and imposed on them over $75,000 in additional legal fees. *See* 130 Cong. Rec. S8017 (daily ed. June 21, 1984). The District Court entered summary judgment for University Hospital and the parents. (Pet. App. 11a.) On February 23, 1984, the Court of Appeals affirmed, rejecting the Department's claim of authority to investigate Baby Jane Doe's parents and University Hospital. The Court of Appeals held that Section 504 does not "apply to treatment decisions involving defective newborn infants." (Pet. App. 40a.) The Secretary did not petition this Court for review of the Court of Appeals' decision in *University Hospital.*

The final 504 Regulation at issue in this proceeding was promulgated by the Secretary on January 12, 1984, while the *University Hospital* case was pending before the Court of Appeals.[9] After publication of this final 504 Regulation and after the Court of Appeals decision in *University Hospital,* the AMA *et al.* filed this action on March 12, 1984, in the District Court for the Southern District of New York.[10] On May 23, 1984, the District Court issued a memorandum and order which held that,

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[9] The Secretary's investigation and initiation of court action in *University Hospital* were undertaken in the fall of 1983 pursuant to her general authority under Section 504 but in the absence of a specific implementing regulation. The final 504 Regulation was not adopted until January 12, 1984, after the *University Hospital* case had been briefed, argued and submitted to the Court of Appeals for decision.

[10] On the same day, the American Hospital Association, the Hospital Association of New York State and Strong Memorial Hospital, which had previously filed an action in the same court challenging the validity of the Secretary's March 7, 1983 interim rule (48 Fed. Reg. 9630 (1983)) amended their complaint to state a claim challenging the lawfulness of the final 504 Regulation.

under authority of *University Hospital*, the 504 Regulation was invalid because the Secretary "has no authority under Section 504 to investigate or to otherwise regulate treatment decisions involving impaired newborn infants." (Pet. App. 51a.) The Court of Appeals, also relying on the controlling effect of *University Hospital*, affirmed in a two paragraph order. (Pet. App. 2a.)

(5) *The Child Abuse Amendments of 1984.* After holding that neither the express language nor the legislative history of Section 504 authorized the direct federal intrusion into historic state functions contemplated by the Secretary, the Court of Appeals concluded its opinion in *University Hospital* by noting (Pet. App. 40a-41a) that:

> it is congress, rather than an executive agency, that must weigh the competing interests at stake in this context in the first instance. Until congress has spoken, it would be an unwarranted exercise of judicial power to approve the type of investigation that has precipitated this lawsuit.

Following the invalidation of the 504 Regulation in this case, the Congress last year undertook just such an examination. It chose not to revive the direct federal investigatory and regulatory role advanced by the Secretary and voided by the courts.

Instead, the Congress in the fall of 1984 enacted the Child Abuse Amendments of 1984, Pub. L. No. 98-457, 98 Stat. 1749 (1984), amending the Child Abuse Prevention and Treatment Act, 42 U.S.C. §§ 5101 *et seq.* In contrast to Section 504, the Child Abuse Prevention and Treatment Act is a state grant program which seeks to help state child protective service agencies discharge *their* responsibilities with respect to abused and neglected children in the context of severely impaired newborn infants.[11] As a principal sponsor of the 1984 Child Abuse

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[11] The 1984 Child Abuse Amendments contemplate grants to state child protective service agencies conditioned on incorporation of

Amendments stated in a crucial piece of the legislative history:

> Throughout the statutory language and accompanying explanatory material, we refer to *authority under state law* as the mechanism for pursuing legal remedies under our amendment. *This legislation does not itself authorize direct federal involvement in individual cases.*[12] (Emphasis supplied.)

The Congress recognized that in enacting the 1984 Amendments, it was, for the first time, expressly addressing the difficult issues arising out of treatment of impaired newborns. In floor debates on the Conference Report, Representative Bartlett stated that "these Baby Doe provisions are *precedent setting.* They represent the first time that we have successfully legislated in a very sensitive area." 130 Cong. Rec. H10329 (daily ed. September 26, 1984) (emphasis supplied).[13] Moreover, in

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certain changes in state law and procedure consistent with the provisions of the Amendments. A definition of child neglect in the circumstance of withholding treatment from a severely disabled child is set forth; states must adopt certain reporting and other procedures; and the direct federal role is limited to training and a clearinghouse function for information relating to developments in treatment and support services for impaired newborns. *See* H.R. Conf. Rep. No. 1038, 98th Cong., 2nd Sess. (1984). *See also* 130 Cong. Rec. H10327 (daily ed. September 26, 1984); 130 Cong. Rec. S12382 (daily ed. September 28, 1984) (conference report debates on floor of House and Senate).

[12] Letter from Senator Hatch to Senator Weicker, 130 Cong. Rec. S12392 (daily ed. September 28, 1984). *See also* Pet. 27 (no direct federal role in individual cases is authorized).

[13] Representative Erlenborn noted that the "disabled infants provisions incorporated in the conference report address a myriad of difficult social and ethical issues. The conference agreement is the product of months of painstaking deliberations." *Id.* at H10333. Senators also explained how the Amendments embodied a new approach and an attempt to craft specific provisions to meet difficult problems. *See, e.g.,* 130 Cong. Rec. S12382-83, S12385, S12389 (daily ed. Sept. 28, 1984) (remarks of Senators Hatch, Dodd and Cranston).

the preamble to the final regulation implementing the 1984 Child Abuse Amendments ("1984 Child Abuse Regulation"), the Secretary noted the special and explicit Congressional effort to deal with the complex problems in this sensitive area (50 Fed. Reg. 14879 (April 15, 1985)):

> [T]his legislation [the 1984 Child Abuse Amendments] was the product of an extraordinary effort on the part of several Senators and Congressmen and representatives of a wide range of medical, right-to-life and disability organizations to forge a substantial consensus on an effective and workable program to assure the provision of appropriate medical care to disabled infants. . . .
>
> *It is clear that the legislation represented a careful balance between the need to establish effective protection of the rights of disabled infants and the need to avoid unreasonable governmental intervention into the practice of medicine and parental responsibilities.* (Emphasis supplied.)

REASONS FOR DENYING THE PETITION

In contrast to the 1984 Child Abuse Amendments enacted by the Congress, the 504 Regulation promulgated solely by the Secretary reflects neither clear congressional authorization nor a careful balancing of the relevant interests. Accordingly, this case does not warrant plenary review by this Court.

First, the Secretary's attempt to investigate and regulate individual treatment decisions involving impaired newborns is clearly not authorized by the language of Section 504. Parents are not recipients of "federal financial assistance" and their treatment decisions on behalf of their infants may not be regulated under Section 504. Similarly, the independent state law duties regarding parental neglect imposed on health care providers are not part of any federally funded "program or activity," and providers' decisions whether to report or prosecute par-

ents for medical neglect are similarly outside the scope of Section 504. Moreover, the Congress clearly did not intend to subvert the historic state law framework for regulating parent-child and doctor-patient relationships and create a body of "504 malpractice law" for determining, according to federal standards, the reasonableness of individual treatment decisions.

Second, there is no substantial federal interest in the voided regulations because, *inter alia*, the Secretary has shown no problem with the historic state law framework that justifies a direct federal role, and the Congress has explicitly and recently adopted an alternative state-based approach in the 1984 Child Abuse Amendments.

I. THE DECISION BELOW WAS CLEARLY CORRECT: SECTION 504 DOES NOT AUTHORIZE DIRECT FEDERAL INVESTIGATION AND REGULATION OF INDIVIDUAL TREATMENT DECISIONS INVOLVING IMPAIRED NEWBORNS.

With respect to "treatment" of impaired newborns, there are three types of decisions which the Secretary's petition seems to suggest are within the scope of Section 504: [14] the decision by parents whether or not to consent to treatment for their child (Pet. 6); the decision by a health care provider whether or not to report to state agencies, or seek state court action against, a parent on grounds of medical neglect (*id.*); and the decision by a physician or hospital whether or not to treat an infant if the parents have consented to treatment (*id.* at 11-12, 19-20). But, despite the Secretary's studied vagueness as to what conduct by whom actually violates Section 504, the Congress clearly intended that none of these types of decisions should be directly regulated by HHS under authority of that provision.

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[14] Section 504 provides, in pertinent part: "No otherwise qualified handicapped individual in the United States . . . shall, solely by reason of his handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial Assistance . . . ." 29 U.S.C. § 794.

A. Treatment Decisions by Parents on Behalf of Their Impaired Newborn Infants Are Not Within the Scope of Section 504.

Although the Secretary withholds this fact from the Court, she has conceded elsewhere that, absent state court action, parents are the sole decisionmakers for their infant children and that parental treatment decisions on behalf of impaired newborns are not within the scope of Section 504 because parents are not recipients of "federal financial assistance."

As noted, parents have the ultimate responsibility for making decisions about the treatment of seriously ill newborns.[15] As the Secretary recently stated in the preamble to the Child Abuse Regulation,

> The decision to provide or withhold medically indicated treatment is, except in highly unusual circumstances, made by the parents or legal guardian. *Parents are the decision makers concerning treatment for their disabled infant, based on the advice and reasonable medical judgment of their physician (or physicians)*. (Emphasis supplied.)

50 Fed. Reg. 14880 (April 15, 1985). Indeed, physicians, nurses and hospitals have no authority to perform treatment on newborn infants to which parents have not consented on behalf of their child.[16]

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[15] State law has always recognized the parents' inherent right to make medical decisions on behalf of their minor children. *See, e.g., Bennett* v. *Jeffreys*, 40 N.Y.2d 543, 356 N.E.2d 277 (1976); *In re Hudson*, 13 Wash. 2d 673, 126 P.2d 765 (Wash. 1942). Parental autonomy to make decisions for their children is also protected under the Constitution. *See, e.g., Wisconsin* v. *Yoder*, 406 U.S. 205 (1972); *Meyer* v. *Nebraska*, 262 U.S. 390 (1923); *Pierce* v. *Society of Sisters*, 268 U.S. 510 (1925).

[16] A physician or hospital is guilty of assault and battery if surgery is performed on an infant without parental consent. *See* Prosser and Keeton on the Law of Torts § 18, at 116 (W. Keeton ed. 1984). *See also Schloendorff* v. *Society of New York Hospital*, 211 N.Y. 125, 105 N.E. 92 (1914).

After conceding that, absent a court order, only parents can make treatment decisions for their infant children, the Secretary then makes the further, devastating concession that parental decisionmaking is outside the scope of Section 504 because parents are not recipients of "federal financial assistance." In the preamble to the 504 Regulation voided below, the Secretary stated:

> Section 504 applies only to programs or activities receiving federal financial assistance; *it does not apply to decisions made by parents.*

49 Fed. Reg. 1631 (1984) (emphasis supplied.) Similarly, in the interpretative guidelines to the 504 Regulation, the Secretary stated unequivocally:

> Section 504 and the provisions of this part *are not applicable to parents (who are not recipients of Federal financial assistance).*

Id. at 1653 (emphasis supplied.) (Pet. App. 67a.)

Accordingly, the Secretary's argument (Pet. 12-18) that the terms of Section 504 clearly authorize direct federal investigation and regulation of treatment decisions involving impaired newborns is fatally flawed by her own explicit concessions that (a) parents, not health care providers, make treatment decisions on behalf of newborn infants, and (b) parents are not federal fund recipients and, thus, not within the scope of Section 504. Indeed, these concessions, made after briefing and argument in *University Hospital*, completely invalidate her own actions in that case, because there HHS was attempting to investigate and regulate directly decisions by Baby Jane Doe's parents.[17] *See* pp. 9-10, *supra.*[18]

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[17] Given the decision of the state child protective service agency not to proceed against Baby Jane Doe's parents (Pet. App. 8a), the Secretary could hardly have been arguing in *University Hospital* that she needed to investigate whether the physicians or hospital had failed to report alleged parental neglect to state authorities.

[18] In light of the Secretary's own explicit concessions about the inapplicability of a federal law triggered by receipt of federal

B. Decisions by Health Care Providers on Whether or Not to Report Suspected or Known Instances of Parental Medical Neglect to State Authorities Are Not Within the Scope of Section 504.

Given her fatal recognition in the 504 Regulation that the federal government has no authority under Section 504 to regulate parental treatment decisions, the Secretary attempts in the Regulation to do indirectly what she has conceded she cannot do directly. Section 84.55(c) of the Regulation (Pet. App. 57a) requires

> that health care providers report on a timely basis *to the state agency* circumstances which they determine to constitute *known or suspected instances of unlawful medical neglect* [by parents] of handicapped infants. (Emphasis supplied.)

Similarly, the interpretative guidelines to the 504 Regulation state (Pet. App. 67a):

> Whenever parents make a decision to withhold consent for a medically beneficial treatment or nourishment, . . . providers [who receive federal financial assistance] may not, solely on the basis of the infant's present or anticipated future mental or physical impairments, fail to follow applicable [state] procedures on reporting such incidents to the state child protective services agency or to seek judicial review [in state court].

See also Pet. 24-25. In other words, under putative authority of Section 504, the Secretary intends to investigate in individual cases whether health care providers

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funds to parental treatment decisions, Judge Winter's statement in his *University Hospital* dissent—that "denial of medical treatment to an infant because the infant is black is not legitimated by parental consent"—is clearly in error. (Pet. App. 44a.) Regardless of the race, color or creed of an infant, health care providers have no authority to operate on a child without parental consent or without a court order removing the parent as decision maker for the child, and neither Title VI of the Civil Rights Act of 1964, 42 U.S.C. §§ 2000d *et seq.*, nor Section 504 alters this fundamental rule.

are discharging their mandatory statutory duties under *state* child neglect laws to report parents to state agencies or sue parents in state courts. *See* p. 8, *supra*. But this contorted position, invalidated below, does not warrant review by this Court.

First, health care providers' decisions whether to report or prosecute parents under *state* child neglect laws are clearly outside the express terms of Section 504 because those decisions are not part of a "program or activity" receiving "federal financial assistance." The Secretary makes no showing either in her petition (*see* p. 15 n. 12) or in the preamble to the 504 Regulation that health care providers' independent, mandatory duties under *state* child neglect statutes are part of Medicaid, 42 U.S.C. § 1395 *et seq.*, Medicare, 42 U.S.C. § 1396 *et seq.*, Hill-Burton, 42 U.S.C. § 291 *et seq.*, or any other federally funded "program or activity." And she can make no such showing. Independent state law duties of health care providers are simply not part of a federal "program or activity" and therefore may not be regulated by the Secretary under Section 504. *Cf. Grove City College* v. *Bell*, 104 S. Ct. 1211 (1984) (construing narrowly "program or activity" language of Title IX of the Education Amendments of 1972, 20 U.S.C. § 1681(a)).

Second, nothing in the legislative history of Section 504 suggests that it was intended to make independent state-law duties a part of a fund recipient's federally financed "program or activity." The essence of Section 504 is to prevent recipients of federal funds—in this case federal health care funds—from denying otherwise qualified handicapped individuals "access" to the programs in which the recipient receives such funds. *Alexander* v. *Choate*, 105 S. Ct. 712, 721 (1985). *See also* S. Rep. No. 1135, 92nd Cong., 2d Sess. 49 (1972). Here, by contrast, the Secretary is trying to force health care providers to provide severely impaired infants "access" to state administrative or judicial processes so that these infants may have their parents' fitness determined by state agen-

cies or state courts under state "medical neglect" standards. *Nothing in Section 504, or its legislative history, suggests the provision was intended to provide such access to state administrative or judicial processes for determinations under state law standards.* Indeed, the Secretary does not—and cannot—cite a single shred of legislative history or a single judicial precedent contemplating or authorizing such a contorted use of Section 504, a federal civil rights statute, to enforce independent state law duties of federal fund recipients. *See* Pet. 18-21 (discussion of legislative history).

Third, while conceding that she cannot directly investigate or regulate parental treatment decisions, the Secretary—by trying to oversee the state law duties of health care providers to refer parental neglect to state agencies or courts—is indirectly using federal power to force others to review and possibly supplant the exercise of parental authority. This she simply may not do under the well-established principle that federal departments and agencies may not do indirectly what they are forbidden by statute from doing directly. *See, e.g., Sunray Mid-Continent Oil Co.* v. *FPC*, 364 U.S. 137, 151-152 (1960). The Secretary cannot regulate parental decisions under Section 504, and she cannot force health care providers to do it for her. Fourth, as discussed in the next section, Congress did not intend when it enacted Section 504 to authorize the creation of a body of "504 malpractice law" for determining whether a health care provider's decision not to report parents to state child neglect authorities in individual cases was a "reasonable medical judgment" or "unreasonable discrimination" under Section 504.[19]

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[19] The decision whether or not to report parents for alleged medical neglect is much more complicated and much more intertwined with medical practice in cases involving impaired newborns than in cases involving denial of treatment by parents on religious grounds. *See* Pet. 20, 25. In the latter case, the effects of medical treatment are crystal clear and the only bar is the religious convictions of the parents. In cases involving impaired newborns, parental decisions not to treat and providers' decisions not to re-

C. Providers' Treatment Decisions In Individual Cases Are Not Within the Scope of Section 504.

The Secretary also maintains that "not every decision by a hospital that happens to relate to the furnishing of medical treatment is perforce a bona fide medical judgment. . . ." Pet. 19. In other words, the Secretary asserts her power, under Section 504, to use officials in HHS's Office for Civil Rights, who may not even have the advice of medical consultants, to investigate and determine whether a provider's decision not to treat in an individual case, if parental consent is given, constitutes a "reasonable medical judgment." *See* 49 Fed. Reg. 1632, 1634 (1984) (504 to be applied in this context on "case-by-case" basis but no commitment to use medical consultants). But, this position is not worthy of review by this Court for several related reasons.

First, the fundamental problem with the Secretary's position is that it is based on a situation that has not occurred—and will not occur—in real life. As we already have explained, parents, not physicians and other providers, have sole legal authority to decide whether or not a child receives medical treatment. For the Secretary's hypothetical to occur, parents, in consultation with their child's physician, would have to authorize treatment for the impaired infant and the physician or hospital would then have to refuse to provide it to an "otherwise qualified" child on the basis of the child's handicap alone. Such a sequence of events is implausible on its face.

Not surprisingly, the Secretary cites no case where this has occurred.[20] In fact, nothing in its regulatory history

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port such parents are based on much more complicated medical determinations about the prognosis for the child even after treatment. *See* pp. 5-6, *supra*.

[20] As the Court of Appeals noted in *University Hospital*, "Baby Jane Doe has been treated in an evenhanded manner at least to the extent that the hospital has always been and remains willing to perform the dual, corrective surgeries if her parents would consent." (Pet. App. 39a.) *See also* pp. 27-28, *infra* ("Baby Doe of

suggests that the purpose of the voided 504 Regulation was intended to deal with this type of situation. *See* Pet. App. 66a-77a. Instead, the interpretative guidelines to the 504 Regulation make clear that it is aimed at parental "neglect" and the duty of health care providers to report such alleged "neglect." *See also* Pet. 24 (Secretary's efforts aimed at parental withholding of consent); 49 Fed. Reg. 1631 (1984) (same). Thus, the Secretary does not need the extensive regulatory regime she has created through this Regulation, which is designed to deal with known or suspected cases of parental "neglect," in order to respond instead to the nonexistent problem of physicians who refuse to treat handicapped infants after parental consent is given.

Second, when it enacted Section 504, the Congress clearly did not authorize creation of a body of "504 federal malpractice" law. But that is precisely what will occur under the Secretary's approach if HHS civil rights officials attempt to determine whether a provider's decision constituted a "reasonable medical judgment" or "unreasonable *discrimination*" under Section 504. The Secretary's glib statements that this distinction is easy to draw (Pet. 14-15, 20) and that Congress intended such line drawing are simply wrong. As the Court of Appeals stated concisely (Pet. App. 30a-31a):

> . . . in arguing that Baby Jane may have been "subjected to discrimination" the government has taken an oversimplified view of the medical decision-making process. Where the handicapping condition is related to the condition(s) to be treated, it will rarely, if ever, be possible to say with certainty that a particular decision was "discriminatory". It is at this point that the analogy to race, relied on so heavily by the dissent, breaks down. *Beyond the fact that no two cases are likely to be the same, it would invariably require lengthy litigation primarily involving conflicting expert testimony to determine whether*

Indiana" case relied upon by Secretary did not involve physician refusal to treat).

> *a decision [by a physician] to treat, or not to treat, . . . was based on a "bona fide medical judgment", however that phrase might be defined. Before ruling that congress intended to spawn this type of litigation under section 504, we would want more proof than is apparent from the face of the statute.* (Emphasis supplied.)

The Court of Appeals' succinct discussion of the legislative history of Section 504 indicates clearly that Congress did *not* intend HHS to determine when a physician's refusal to treat was reasonable or unreasonable—a question closely akin to the one asked in medical malpractice cases brought under state law. (Pet. App. 31a-35a.)[21]

Indeed, the Secretary does not cite a single passage from the legislative history indicating that Congress contemplated such an inquiry in *individual* medical cases by HHS officials.[22] And, although numerous decided cases have interpreted Section 504 in the context of "health care" programs or activities, not one,[23] however, author-

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[21] *See American Academy of Pediatrics* v. *Heckler*, 561 F. Supp. 395, 401 (D.D.C. 1983) ("no congressional committee or member of the House or Senate ever even suggested that section 504 would be used to monitor medical treatment of defective newborn infants or establish standards for preserving a particular quality of life").

[22] The regulatory history of Section 504, as the Court of Appeals in *University Hospital* recognized (Pet. App. 18a-20a), also refutes the Secretary's position. The original 504 regulations clearly rejected any individualized, federal right to treatment. 41 Fed. Reg. 29559 (1976). The references in the general Section 504 regulations to "health services," *see* Pet. 22, reflect a concern with access to federally funded programs and not authorization of a detailed HHS inquiry into the reasonableness or unreasonableness of a medical decision in the context of a multiply handicapped child. 41 Fed. Reg. 29567 (1976) (health services should be "accessible" and "available"). *See also Southeastern Community College* v. *Davis*, 442 U.S. 397, 411 (1979) (Secretary's interpretation of Section 504 entitled to deference only if it "honors" the language, purpose and history of the statute).

[23] Indeed, the Eighth Circuit recently dismissed a Section 504 claim alleging in part that a nursing home had discriminated

izes the kind of "504 federal malpractice" determination in individual cases contemplated by the Secretary here.

Third, sound principles of statutory construction require rejection of the Secretary's attempt to regulate health provider decisions in this area. This Court in a long line of decisions has held that "unless the Congress conveys its purpose clearly, it will not be deemed to have significantly changed the federal-state balance" in areas where the states have historically regulated. *United States* v. *Bass*, 404 U.S. 336, 349 (1971).[24] *Cf. Pennhurst State School & Hospital* v. *Halderman*, 451 U.S. 1, 17 (1981). *See also Alexander* v. *Choate*, 105 S. Ct. 712, 720 (1985) (importance of interpreting § 504 so as to keep it "within manageable bounds"). As noted above, state licensure, child neglect and other laws require that health care providers report instances of parents' medical neglect and not refuse to treat their patients unless notice is given and other treatment is available. *See* p. 4, *supra*. The Secretary's attempt to regulate, under Section 504, providers' decisions whether to treat after parental consent demonstrably intrudes on this area of historic state concern without the requisite clear expression of intent

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against a resident by failing to provide adequate medical care, concluding that "[i]n substance, this is a medical malpractice case" not cognizable under Section 504. *Hoyt* v. *St. Mary's Rehabilitation Center*, 711 F.2d 864, 867 (8th Cir. 1983). The cases that have considered Section 504 claims in the health care field have dealt with such issues as employment, *e.g.*, *United States* v. *Cabrini Medical Center*, 639 F.2d 908 (2d Cir. 1981), admission to medical schools and other medical training programs, *e.g.*, *Southeastern Community College* v. *Davis*, 442 U.S. 397 (1979), and reduction in medicaid assistance or other federally-supported medical insurance and benefits, *e.g.*, *Alexander* v. *Choate*, 105 S. Ct. 712 (1985).

[24] *See, e.g., Apex Hosiery Co.* v. *Leader*, 310 U.S. 469, 513 (1940); *FTC* v. *Bunte Brothers, Inc.*, 312 U.S. 349, 354-355 (1941). *See also United States* v. *Culbert*, 435 U.S. 371, 378 (1978); *Heublein, Inc.* v. *South Carolina Tax Commission*, 409 U.S. 275, 281-283 (1972).

by the Congress to alter the historic federal-state balance. This regulation is thus outside the scope of her authority.

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In sum, Section 504 clearly does not authorize the Secretary's attempt to investigate and regulate directly parental decisions concerning treatment of their severely impaired infants, providers' decisions about whether to refer parents to state authorities for parental neglect determinations or providers' decisions whether or not to treat if parental consent is given. Because the Court of Appeals reasonably concluded that the Secretary's regulatory approach is so demonstrably beyond the scope of her authority under Section 504, further review by this Court is not warranted.

II. THERE IS NO SUBSTANTIAL FEDERAL INTEREST IN THE VOIDED REGULATION.

The petition should also be denied because there is no substantial federal interest in the voided regulation.

A. The 1984 Child Abuse Amendments, Not the Secretary's Intrusive Regulatory Approach, Represent The Federal Interest In This Sensitive Area.

In contrast to the challenged regulatory approach adopted solely by the Secretary, the 1984 Child Abuse Amendments, as the Secretary concedes, represented an "extraordinary effort" to develop a consensus on the part of the Congress and constituted a "careful balance" between protecting severely impaired newborns and avoiding "unreasonable governmental intervention" into the practice of medicine and parental responsibilities. 50 Fed. Reg. 14879 (April 15, 1985). In contrast to the Secretary's intrusive federal regulatory approach, the 1984 Child Abuse Amendments augment existing state child protective services, rather than subverting them with a duplicative and inconsistent federal role. *Id.* at 14883 (clear intent of Congress that states use existing child protective system to carry out amendments). This considered, balanced and explicit Congressional enactment

reflects a clear Congressional intent, on policy grounds, *not* to follow the Secretary's regulatory approach in a number of important ways.

Unlike the Secretary's intrusive regulatory approach, the Congress clearly did not want a direct federal role in investigating and regulating individual cases, as the Secretary concedes in the 1984 Child Abuse Regulation, *id.* at 14885:

> The *major difference* between the section 504-based approach and that of the Child Abuse Amendments of 1984 is that the former is *implemented and enforced directly by the Federal government*, whereas the latter, within the framework of the Child Abuse Prevention and Treatment Act, relies on State implementation and enforcement regarding individual instances of child abuse and neglect. . . . (Emphasis supplied.)

As the Secretary further concedes, the legislative history of the 1984 Child Abuse Amendments clearly indicates that the Congress did not want a "new system and a new bureaucracy" created at the federal level to deal directly with the issue of treatment for impaired newborns. *Id.* at 14881.

Unlike the Secretary's intrusive regulatory approach, the Congress also did not want the creation of "*federally-prescribed medical standards* for approved treatment for specific cases." *Id.* at 14880 (emphasis supplied).[25] Such federally prescribed standards are the inevitable result of direct federal inquiry under Section 504 into the reasonableness of parental or physician decisions regarding treatment of impaired newborns.

Finally, unlike the Secretary's regulatory approach, which utilizes direct federal hotlines for the reporting of

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[25] As the Senate sponsors of the 1984 Child Abuse Amendments stated in a letter to the Secretary dated March 13, 1985, the "individuality of each case and the complexities of the medical situations associated with each case make it unwise, we believe, to establish any 'standard' form of treatment for a particular type of case." *See* 50 Fed. Reg. 14879-80 (April 15, 1985).

cases to HHS officials, the Congress in the 1984 Child Abuse Amendments did not want such federal hotlines or any regulation of the internal affairs of hospitals. As the Secretary concedes in the 1984 Child Abuse Regulation, *id.* at 14883, "matters relating to the internal affairs of hospitals are beyond the scope of this regulation." *See also id.* at 14884.

In sum, the Congress in the fall of 1984—after *University Hospital* was finally decided and after the 504 Regulation was voided—clearly addressed the question of what federal response was appropriate with respect to the tragic question of providing appropriate treatment to severely impaired newborns. It explicitly adopted a state-based approach that, in all its particulars, rejected on policy grounds the direct federal role adopted solely by the Secretary in her 504 Regulation. Given this recent and clear legislative statement by the Congress of the federal interest in this sensitive area, further review of the validity of the Secretary's intrusive administrative approach is not warranted.[26]

B. The Secretary Has Shown No Problem With the Historic State Law Framework That Warrants Direct Federal Investigation and Regulation.

After extensive hearings, the taking of written testimony and extensive deliberations, the President's Com-

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[26] Although the Secretary asserts (Pet. 27 n.22) that the "new amendments do not, either practically or legally, obviate the need for review in this case," this claim is clearly wrong. Congress did include a provision in the Amendments indicating that they did not affect any rights under Section 504. Section 127(a), 98 Stat. 1754. But if Congress had concluded that a direct federal involvement in this area—in addition to the role of parents, doctors, nurses, hospitals, and state authorities—was appropriate, it surely would have ratified the Secretary's interpretation rather than enacting new state-based legislation and creating legislative history which explicitly rejects, on policy grounds, the Secretary's direct federal approach. As a "practical" matter, the 1984 Child Abuse Amendments should take effect; if a direct federal role is necessary under Section 504, Congress can in the future provide the explicit authorization for such a role that is so clearly absent here.

mission Report (p. 209 & n.51) concluded that erroneous parental decisions about the treatment of newborns appears to be "very rare." The Report described no instances where health care providers failed to report parental neglect or refused to provide treatment to which parents had consented. Most importantly, the Secretary herself, in the preamble to the 504 Regulation, described the status of 49 cases in which HHS had investigated reports of possible "discrimination" under Section 504 with respect to impaired newborns. Although investigations had not been completed in all the cases, the Secretary concluded that "no case has resulted in a finding of discriminatory withholding of medical care." 49 Fed. Reg. 1649 (1984).

Moreover, in her petition, the Secretary does not remotely make the case that there is any problem with parental decisions or decisions by health care providers which warrants direct federal intrusion. *See* Pet. 2-3, 26.[27] Instead, the Secretary tries to mislead this Court by vaguely (and almost exclusively) citing to the "Baby Doe of Indiana" case ("Bloomington Baby Doe"), as if this case represented the kind of Section 504 "discrimination" which would be remedied by a direct HHS role. But in that situation, where a newborn with Down's Syndrome died after parents refused to authorize surgery to repair a blocked esophagus, the child's doctors initially followed the parents' decision yet the case was nevertheless referred to the hospital for further discussion. The hospital then sought judicial review of that parental non-

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[27] For example, the Secretary's citation to the preamble to the final 504 Regulation, 49 Fed. Reg. 1649 (1984), simply references the 49 cases investigated by HHS which yielded no finding of "discrimination" under Section 504. Pet. 26. Moreover, the Secretary's claim in the petition that a problem exists requiring a direct federal role is directly contradicted by her statement in the 1984 Child Abuse Regulation that "only a very small fraction of births involve any serious question of survival" and only "a fraction" of this tiny fraction would "involve even a potential allegation of medical neglect" under *state* law. 50 Fed. Reg. 14886-87 (April 15, 1985).

treatment decision. The state court decided that the parents had made a reasonable decision between treatment options. The county department of public welfare reviewed the case and decided not to challenge the judge's order further. The county prosecutor then brought a second action. And a second state court judge refused to find parental neglect.[28] In short, hospital and state authorities actively sought review of the parents' decision and two separate state court decisions supporting the parents were rendered. Accordingly, this case shows active provider and state involvement in a case of questionable parental decisionmaking—and does not remotely support the Secretary's claim that an additional level of direct federal intrusion is necessary.

Finally, not only are formal state laws and procedures functioning as intended, but the development of voluntary, hospital-based infant care review committees, *see* p. 7, *supra*, underscores that a direct federal investigatory and regulatory role is unnecessary. Indeed, as the Secretary conceded in the 1984 Child Abuse Regulation, use of these committees should reduce the need for formal *state* legal proceedings involving impaired newborns to a "[v]ery few cases." 50 Fed. Reg. 14887 (April 15, 1985). It follows *a fortiori* from this concession that there is no need for an intrusive, duplicative HHS 504 bureaucracy to investigate directly possible Section 504 violations in this sensitive area.

C. Direct Federal Investigation and Regulation In This Sensitive Area Has Caused, And Will If Reinstated Cause, Harm.

The Secretary's actions in *University Hospital* and her other 48 direct federal investigations under Section 504 perfectly illustrate the harm that is caused by a direct federal role that, in effect, duplicates and attempts to

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[28] *See In re Infant Doe*, No. GU 8204-004A (April 12, 1982), writ of mandamus dismissed *sub nom. State ex rel. Infant Doe* v. *Baker*, No. 482 S 140 (Ind. May 27, 1982). *See also* J. Lyon, Playing God in the Nursery 21-39 (1985).

second-guess decisions made by parents, providers and state authorities. In *University Hospital*, the federal government pressed its own duplicative, harassing effort even after relevant state agencies and state courts determined that there were no grounds for state intervention. Most of the Secretary's other investigations have been equally intrusive, although none has resulted in a finding of discrimination under Section 504. 49 Fed. Reg. 1646-1649 (1984).[29] Moreover, by imposing on health care providers vague and confusing federal obligations—which are different than, Pet. 27 n.22, and may conflict with their duties under state law—the Secretary's regulatory approach has distorted medical decisionmaking. The uncertain and conflicting nature of these independent federal duties may lead to overtreatment which will only prolong the suffering of an impaired infant and which will preclude use of scarce infant intensive care units for newborns who could genuinely benefit from treatment.[30]

CONCLUSION

The interests of severely impaired newborns are protected by their parents, by infant care review committees, by the duties of health care providers under state law, by state child protective service agencies and by

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[29] Even HHS' cursory description of these investigations, *id.*, makes clear that they have resulted in invasions of family privacy, medical records and confidential medical decisionmaking, and have disrupted hospital operations and delayed ongoing treatment for impaired newborns and other patients. *See also* Affidavit of Ervin E. Nichols, M.D., Director of Practice Activities of the American College of Obstetricians and Gynecologists, ¶ 11; Affidavit of Rita G. Harper, M.D., Chief of Perinatal Medicine, North Shore University Hospital, ¶ 15; Auld Affidavit, note 6, *supra*, ¶ 18; Shapiro & Rosenberg, *The Effect of Federal Regulations Regarding Handicapped Newborns: A Case Report*, 252 J.A.M.A. 2031 (1984); Strain, *The American Academy of Pediatrics Comments on the "Baby Doe II" Regulations*, 309 New Eng. J. Med. 443 (1983).

[30] Auld Affidavit, note 6, *supra*, ¶¶ 9, 21; Affidavit of Hubert A. Ritter, M.D., clinical professor of obstetrics and gynecology, St. Louis University School of Medicine, ¶¶ 10-11.

state courts. Neither Section 504, nor any substantial federal interest, justifies the direct and intrusive federal investigation and regulation of treatment decisions involving impaired newborns advocated by the Secretary.[31]

Accordingly, for the reasons stated above, respondents AMA *et al.* respectfully request that the Secretary's petition for a writ of certiorari be denied.

Respectfully submitted,

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[31] Contrary to the Secretary's claims, Pet. 12, 27-28, the holding of the Court of Appeals in *University Hospital* and this case—which is by its terms confined to *treatment* decisions involving *severely impaired newborns*—does not control the application of Section 504 to other decisions involving impaired newborns, other treatment decisions involving non-infants, or general policies or procedures regarding federally funded health care or other programs. Nor *a fortiori* does it control any interpretation of Title VI of the Civil Rights Act of 1964. *See Consolidated Rail Corp.* v. *Darrone*, 104 S. Ct. 1248, 1254 n.13 (1984) (recognizing distinctions between Title VI and § 504). Moreover, other than the decisions in this case, no reported decisions of any court have relied upon the holding of *University Hospital*, decided more than a year ago, in any of the other contexts cited by the Secretary.

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